

## REMARKS

Claims 1-14 remain pending in the application.

All of the amendments to the specification and abstract are fully supported by the original disclosure of this application and therefore do not constitute the introduction of any new matter into this case. The original Abstract has been canceled in its entirety and substituted by a new Abstract which is believed to provide a more concise summary of the disclosure in accordance with U.S. practice format.

The Examiner objected to the drawings because reference element 11, as described in the specification, was not shown in the drawings. It appears that the Examiner may be referring to informal drawings that may have been filed with the application. In this regard, the Examiner will note that new formal drawings have been submitted, which clearly shows reference element 11 in Figure 1. Withdrawal of the drawing objection is respectfully requested.

## CLAIM REJECTIONS

### Claim Rejections under 35 U.S.C. § 112

Claims 2, 3 and 6 are rejected under 35 U.S.C. § 112, second paragraph.

The Examiner will note that the "blind housing" refers to reference element 11, as shown in Figure 1, which simply refers to a bore with an end which is closed. It is most respectfully believed that the term "blind housing" is not a relative term, and the specification has been amended to specifically describe what this term refers to.

Withdrawal of the rejection is most respectfully requested in view of the remarks above, and the amendments to the specification.

### Claim Rejections under 35 U.S.C. § 102

Applicant wishes to direct the Examiner's attention to MPEP § 2131 which states that to anticipate a claim, the reference must teach every element of the claim. "A claim

is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed.Cir. 1990).

Claims 1-5, 7 and 9 are rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. 5,899,941 (hereinafter Nishijima et al.). In the device of Nishijima et al., the Examiner will note that the equated first plate 2 is integrally connected with the equated spherical cap 11. In contrast, in the claimed device, the first plate 2 includes a blind housing 11 into which the first insert 5 having a spherical cap 6 is inserted therein.

Further, the Examiner will note that in the device of Nishijima et al., as shown in Figure 10A, the equated spherical cup 15 includes an actual contact area (with the equated spherical cap 11) that is clearly less than the contact area of the equated spherical cap 11. In contrast, in the claimed device, the spherical cup 8 has a contact area that is not less than the contact area of the spherical cap 6, as shown in Figures 1 and 5. The Examiner will note that the actual contact area of the equated spherical cup 15 of Nishijima et al. is always smaller than the contact area of the equated spherical cap 11, as shown also in Figures 5, 6A and 6B.

The Examiner also indicated that the device of Nishijima disclosed an annular molding, wherein the equated spherical cup 15 is connected via the annular molding to the base of the insert. In Figures 10A and 10B, the equated second insert 19 of Nishijima covers the upper face of the equated second plate 3. Hence, the clearance between the upper and lower plates 2, 3 is substantially limited, in comparison with the claimed invention (see Figure 1 of the application). The Examiner also indicated that the device of Nishijima et al. disclosed "an annular setback" to leave clearance for the

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annular molding of the spherical cup during movements of the plates. It is most respectfully believed that the device of Nishijima et al. neither discloses, teaches nor suggests such an annular setback (reference element 18 of the claimed invention), and the Examiner is urged to specifically point out where in the reference to Nishijima et al., the equated annular setback is disclosed. The Examiner will note that in the claimed invention, the annular setback 18 surrounding the housing 11 provides additional clearance for the annular molding 15 of the spherical cup 5 during movements of the plates 2, 3.

Further, the Examiner will clearly note that the main pieces of the device of Nishijima et al. is either two or three, depending on the embodiments. In contrast, in the claimed invention, the number of main pieces of the claimed invention is four (reference elements 2, 3, 5 and 7). Clearly, the reference to Nishijima et al. does not disclose both first and second inserts mounted on the equated plates, as claimed.

Further, in the claimed invention, the inserts 5, 7 are made of ceramic materials that are not in contact with opposing plates 2, 3, so that the rubbing between the inserts always occurs between the inserts, thereby reducing the wear on the inserts, and substantially reducing the likelihood of breakage or cracking of the ceramic inserts. Since the device of Nishijima et al. clearly lacks the elements and advantages of the claimed invention, the device of Nishijima et al. is highly sensitive to the phenomena of breakage or cracking.

In view of the remarks above, withdrawal of the rejection is most respectfully requested.

**Claim Rejections under 35 U.S.C. § 103**

Claims 4, 5, 8-12 and 14 are rejected under 35 U.S.C. § 103 as being unpatentable over Nishijima et al. in view of U.S. 6,019,792 (hereinafter Cauthen).

Applicant most respectfully wishes to direct the Examiner's attention to the basic requirements of a prima facie case of obviousness as set forth in the MPEP. MPEP §

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2131 states that to establish a prima facie case of obviousness, three basic criteria must be met. First there must be some suggestion or motivation, either in the prior art references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine the teachings of the reference. Second, there must be a reasonable expectation of success for the modification. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

Further, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in Applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

MPEP § 2143.03 states that all claimed limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art". *In re Wilson* 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious. *In re Fine* 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

Applicant also most respectfully directs the Examiner's attention to MPEP § 2144.08 which states that Office Personnel should consider all rebuttal argument and evidence presented by the Applicant. *In re Soni*, 54 F.3d 746, 750, 34 USPQ2d 1684, 1687 (Fed. Cir. 1995) (error not to consider evidence presented in the specification).

The Examiner will note that the reference to Nishijima et al. does not disclose, teach or suggest all of the claimed elements of independent claim 1. As such, the reference to Nishijima et al. is most respectfully believed not to be sustainable based on 35 U.S.C. § 102. Hence, even if one were to modify the device of Nishijima et al. to manufacture the surfaces of the equated spherical cap and cup 11, 14, in the manner suggested by the Examiner, the resulting device would not disclose, teach or suggest all of the claimed elements of independent claim 1.

The Examiner acknowledged that the reference to Nishijima et al. does not

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specify "an outer convex surface". The Examiner seeks to modify the reference to Nishijima et al. according to the teachings of Cauthen, in order to provide a convex surface. The Examiner will note that in claim 8 of the claimed invention, the plate extending over the other plate has a top outer surface that presents a profile that is convex in the sagittal plane. In contrast, in the device of Cauthen, as shown in Figures 4a and 4b, the convex outer surfaces are along the length of the vertebrae, and not along the sagittal plane, as claimed.

Withdrawal of the rejection is respectfully requested in view of the remarks above.

**Allowable Subject Matter**

Applicant thanks the Examiner for indicating that claims 6 and 13 would be in condition for allowance if rewritten or amended in independent form.

Since independent claim 1 is believed to be fully patentable over the cited references, it is most respectfully believed that all dependent claims, including claims 6 and 13 are patentable as well. Hence, it is most respectfully believed that rewriting or amending claims 6 and 13 in independent form is not presently necessary.

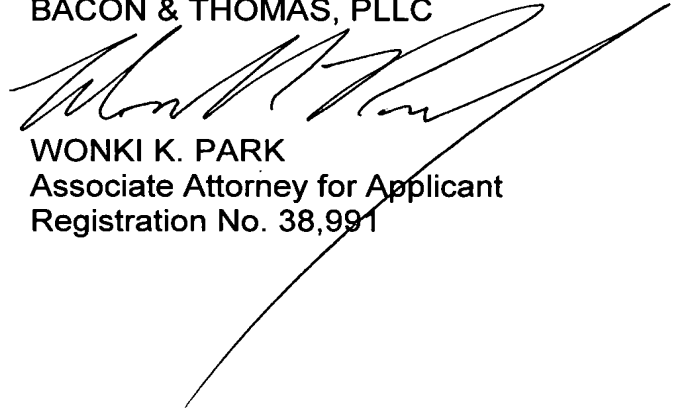
In summary, it is respectfully submitted that none of the prior art individually or collectively shows a disk prosthesis as claimed. Accordingly, withdrawal of the rejection of the claims appears to be warranted and the same is respectfully requested. In the event there are any outstanding matters remaining in the present application which can

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be resolved by a telephone call or facsimile communication to Applicant's Attorney, the Examiner is invited to contact the undersigned by telephone or facsimile at the numbers provided below.

Respectfully submitted,  
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## APPENDIX OF MARKED-UP SPECIFICATION

Page 4, lines 6-31, please amend this paragraph as follows:

As can be seen more clearly in Figures 1 to 4, the subject matter of the invention is a disk prosthesis 1 for implanting as a replacement for a disk between two adjacent cervical vertebrae. The cervical prosthesis 1 of the invention comprises a first plate 2, referred to as a top plate in the example shown, and a second plate 3 referred to as a bottom plate. The plates 2 and 3 are designed to be fixed to adjacent cervical vertebrae and each has a respective outer face 2<sub>1</sub>, 3<sub>1</sub> of dimensions that are substantially similar and adapted to fit approximately to the outlines of the surfaces of the associated joint. Each plate 2 and 3 also has a respective inner face 2<sub>2</sub> and [2<sub>3</sub>] 3<sub>2</sub> that extends to face the other interface. The general shape of each of the plates 2 and 3 is that of a rectangular parallelepiped processing a respective posterior edge 2a, 3a extending at a distance from a respective anterior edge 2b, 3b. The anterior edge 2b, 3b of [the] each plate 2, 3 is connected to the corresponding posterior edge 2a, 3a via two side edges 2c, 3c that are opposite each other. The edges 2a, 2b, 2c, and 3a, 3b, 3c are preferably straight in profile and they are interconnected by rounded corners. The posterior edge 2a, 3a of each plate preferably presents a profile that is convex in a transverse plane T, while the anterior edge 2b, 3b presents a profile that is concave.

Page 4, line 32 through Page 5, line 20, please amend this paragraph as follows:

The cervical prosthesis 1 of the invention also has a ball joint 4 interposed between the two plates 2 and 3 which are mounted in the superposed configuration. The ball joint 4 is constituted by a first insert 5 presenting a spherical cap 6 and by a second insert 7 presenting a spherical cup 8 that co-operates with the spherical cap 6. Each insert 5, 7 is designed to be mounted in a housing 11, preferably a blind housing (which refers to a bore with an end which is closed, as shown in Fig. 1), formed from

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the inside face  $2_2$ ,  $3_2$  of each plate 2 and 3. Each insert 5, 7 is generally circularly symmetrical in shape and possesses a respective base 12, 13 of circular right cross-section, with one of its ends being shaped to present the spherical cap 6 or the spherical cup 8. The right cross-section of the base 12, 13 of each insert 5, 7 is constant, or preferably tapering from the spherical cap 6 or the spherical cup 8. In this preferred embodiment, each reception housing 11 is complementary in shape to the insert 5, 7 so as to enable the inserts 5, 7 to be assembled conically in the plates 2, 3. Naturally, any other type of assembly could be envisaged for the inserts, e.g. by means of adhesive or by means of crimping. In an embodiment, provision might be made to fit a damping element against the end of the blind housing 11 so as to be interposed between the corresponding insert and the plate in order to damp the axial forces acting on the prosthesis.

Page 8, lines 14-27, please amend this paragraph as follows:

As can be seen more clearly in Figures [2] 1 and 4, each plate 2, 3 is provided on its posterior edges 2a, 3a with two positioning holes 22 for the endpieces of a tool that serves to hold both plates simultaneously. It should be observed that in this position, as shown in Figure 1, the plates 2, 3 form an angle in the sagittal plane S to facilitate insertion of the cage into the intersomatic gap. It can be seen that the height  $h$  of the prosthesis 1 at its front face as defined by the anterior edges 2b, 3b is smaller than its height H of its rear portion as defined by the posterior edges 2a, 3a. In accordance with a preferred characteristic the positioning holes 22 in any one plate converge on each other so as to facilitate withdrawal of the positioning tool.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
PATENT APPLICATION

5      Entitled :            A DISK PROSTHESIS FOR CERVICAL VERTEBRAE

Inventors :                **RAMADAN Aymen and BÜHLER Markus**

10      Assignee :                **SCIENT'X (Société à Responsabilité Limitée)**

ABSTRACT OF THE DISCLOSURE

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[The invention relates to a<sup>A</sup> disk prosthesis for cervical vertebrae<sup>TM</sup> ~~the~~ prosthesis ~~being~~ of the type including:] *includes*

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~~Ø~~ a spherical cap formed on a first insert, while a spherical cup is formed on a second insert~~Ø~~,

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~~Ø~~ two inserts made of ceramic material, one of the inserts being mounted on a first plate while the other insert is mounted on a second plate in such a manner that the center of rotation of the joint is substantially centered relative to the edges of the plates~~Ø~~,

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~~Ø~~ a spherical cup possessing a contact surface area that is not less than that of the spherical cap and being connected via an annular molding to the base of the insert~~Ø~~, and  
~~Ø~~ a plate provided with the insert having the spherical cap includes an annular setback to leave clearance for the annular molding.

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